OECD GLOBAL FORUM ON KNOWLEDGE ECONOMY:
BIOTECHNOLOGY

GUIDANCE FOR THE OPERATION OF BIOLOGICAL RESEARCH CENTRES (BRCs)

CERTIFICATION AND QUALITY CRITERIA
FOR BRCs

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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To achieve the highest sustainable economic growth and employment and a rising standard of living in member countries, while maintaining financial stability, and thus to contribute to the development of the world economy.

To contribute to sound economic expansion in member as well as non-member countries in the process of economic development; and

To contribute to the expansion of world trade on a multilateral, non-discriminatory basis in accordance with international obligations.

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CERTIFICATION AND QUALITY CRITERIA FOR BIOLOGICAL RESOURCE CENTRES (BRCs)

Introduction

1. This document provides a framework for the national certification (independent review by third party) of Biological Resource Centres (BRCs) as defined by the OECD (Box 1) and gives general guidelines for its implementation. Compliance with this guidance is mandatory for those bodies that are part of a Global Biological Resource Centre Network.

Box 1. OECD definition of Biological Resource Centres

"Biological Resource Centres are an essential part of the infrastructure underpinning biotechnology. They consist of service providers and repositories of the living cells, genomes of organisms, and information relating to heredity and the functions of biological systems. BRCs contain collections of culturable organisms (e.g. micro-organisms, plant, animal and human cells), replicable parts of these (e.g. genomes, plasmids, viruses, cDNAs), viable but not yet culturable organisms, cells and tissues, as well as databases containing molecular, physiological and structural information relevant to these collections and related bioinformatics."

2. BRCs retain collections of biological material and associated information to facilitate access to *ex situ* biological resources and to ensure that they remain available for sustainable use.

3. Biological resource collections are entities compliant with appropriate national law, regulations, and policies and have been constituted to fulfil many crucial roles, which include:

- Preservation and supply of biological resources for scientific, industrial, agricultural, environmental and medical R&D and biotechnological processes.
- Performance of R&D on these biological resources.
- Conservation of biodiversity.
- Repositories of biological resources for protection of intellectual property.
- Resources for public information and policy formulation.

4. This document is based upon the implementation of the OECD's "Guidance for the Operation of Biological Resource Centres" (2003) which has a two-level approach:

- Part 1: General requirements for the operation of Biological Resource Centres, which is normative for all BRCs that are part of a Global Biological Resource Centre Network (GBRCN).
- Domain criteria, specific to the type of biological material as defined above (Box 1) and mandatory for BRCs that are part of a GBRCN.

- Part 2: Guidance for the operation of Biological Resource Centres: Micro-organism domain.
- Part 3: Guidance for the operation of Biological Resource Centres: Animal cell domain.
- Part 4: Guidance for the operation of Biological Resource Centres: Human cell domain.
- Part 5: Guidance for the operation of Biological Resource Centres: Plant cell domain.

5. Both levels are linked to a mechanism for monitoring and review, based on scientific, technical and administrative expertise.

6. Those biological resource collections that attain national certification through independent review by a third party become members of the Global Biological Resource Centre Network (GBRCCN).

General BRC certification rules

7. To become a BRC within the GBRCN, a candidate biological resource collection (repository) must apply for certification through a process approved by national governments **either** through a certification body recognised by government **or** through a transparent certification procedure recognised by government **or** directly by government.

8. Participating governments will be responsible for ensuring that their respective certification body is independent, qualified and has no conflict of interest with the BRC seeking certification.

9. The certification must be based on the implementation of the authoritative documents selected by national governments and the OECD's "Part 1. Guidance for the Operation of Biological Resource Centres: General Requirements for all BRCs" (2003) and the supplemental domain-specific guidance for the operation of Biological Resource Centres (2003), Parts 2-5.

10. Future revision of the general and domain-specific criteria in these standards may be negotiated and approved by the GBRCN governing council.

Certification mechanisms

11. If a body manages several collections on different sites, each site or collection must meet the relevant general and domain-specific requirements in order to be designated a BRC.

12. The certification procedure must respect the following points:

- The certification body must ensure that the certification procedure is transparent and available to third parties.
- The procedure must include regular revision and be reproducible.
- The applicant must be able to appeal in the event of refusal.
- Certification must be withdrawn if the BRC fails to comply with the necessary applicable standard.

BRC general criteria

13. Certified BRCs must comply with:

- Their national legislation, regulations and policies concerning acquisition, conservation, utilisation, including the fair and equitable sharing of benefits arising from utilisation of genetic resources, and distribution of biological resources and data related thereto.

- The regulations of the relevant countries when moving biological materials across national boundaries.

- The relevant national agreements, regulations, policies, frameworks and recommendations.

14. Certified BRCs must have in place a mechanism that updates their knowledge of the above (paragraph 13).

15. When certification is granted it should indicate the highest level of hazard, where appropriate, that the BRC is qualified to handle.

16. It is anticipated that this document will evolve through further development and input from other sources including stakeholders and certification bodies.